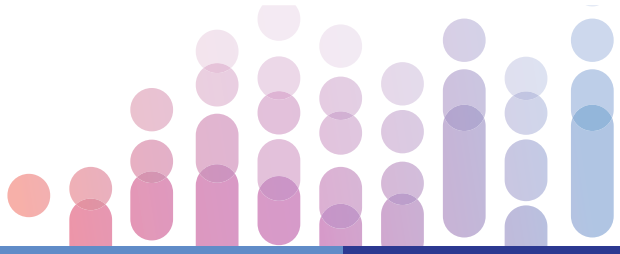
pedmark®
(sodium thiosulfate injection)

Product information



Description	National Drug Code	Package Configuration
12.5 g/100 mL (125 mg/mL) clear, colorless solution in a single-dose vial	73077-010-01	1 vial per carton

Ordering information

PEDMARK is available directly through **specialty distributors** for shipment to medical practices, hospitals, and home health/specialty pharmacies.

AmerisourceBergen

Besse Medical
P 1-800-543-2111
F 1-800-543-8695
E service@besse.com
W besse.com

Oncology Supply
P 1-800-633-7555
F 1-800-248-8205
E service@oncologysupply.com
W oncologysupply.com

ASD Healthcare
P 1-800-746-6273
F 1-800-547-9413
E asd.customerservice@asdhealthcare.com
W asdhealthcare.com

McKesson

McKesson Plasma and Biologics Distribution
P 1-877-625-2566
F 1-888-752-7626
E mpborders@mckesson.com
W connect.mckesson.com

McKesson Specialty Care Distribution
P 1-855-477-9800
E MSH.CustomerCare-MSPL@McKesson.com
W mscs.mckesson.com/CustomerCenter

Cardinal Health

Cardinal Health Specialty Distribution
P 1-855-855-8708
F 1-877-274-9897
E gmb-spd-csorderentry@cardinalhealth.com
W specialtyonline.cardinalhealth.com

STORAGE: Store at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C and 30°C (59°F to 86°F).

For medical inquiries, please call 1-833-FENNEC1 (1-833-336-6321)

INDICATIONS AND USAGE

PEDMARK (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Limitations of Use The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

SELECT IMPORTANT SAFETY INFORMATION

- PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

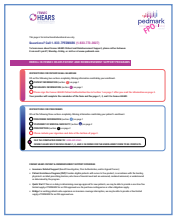
Please see additional Important Safety Information on page 3.

Please see full Prescribing Information in pocket.

Our commitment to patients and providers

FENNEC HEARS™
Hearing Education, Access & Reimbursement Support

To enroll in Fennec HEARS, submit your patient's completed **Enrollment Form**



Insurance-Related Support: Benefits Investigation, Prior Authorization, and/or Appeal Process.

Patient Assistance Program (PAP): Provides eligible patients with access to free product in accordance with the treating physician's on-label prescribing decision. Eligibile patients have a financial need, and are uninsured, rendered uninsured, or underinsured as determined by the program.

Quick Start Program: If there is a delay in determining coverage approval for new patients, we may be able to provide a one-time free, limited supply of PEDMARK for an FDA-approved use. No purchase contingencies or other obligations apply.

Bridge Program: For existing patients who experience an insurance coverage interruption, we may be able to provide a free, limited supply of PEDMARK for an FDA-approved use.

$0

PEDMARK Copay Savings Program
Provides eligible patients with financial assistance to cover out-of-pocket copayment or co-insurance cost associated with their prescription*

FAX THE COMPLETED ENROLLMENT FORM TO 1-888-481-0561

To learn about hearing education or for more information on access and reimbursement support, please call 1-833-773-3627, Monday–Friday, 9am to 6pm ET to speak with a Fennec HEARS Care Coordinator

***PEDMARK Copay Savings Program Terms and Conditions**
Copay support is available to patients with commercial insurance and covers out-of-pocket expenses. Offer is not valid if prescription is paid in part or in full by any state or federally funded health care program, including but not limited to Medicare, Medicaid, VA, Department of Defense, or TRICARE, or where prohibited by law.

SELECT IMPORTANT SAFETY INFORMATION

- Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

Please see additional Important Safety Information on page 3.
Please see full Prescribing Information in pocket.

pedmark® (sodium thiosulfate injection)

REVERSE OF BACK COVER BECOMES INSIDE OF POCKET

THIS MEETS GLUED EDGE A

THIS MEETS GLUED EDGE B

REVERSE OF ISI BECOMES INSIDE OF POCKET

GLUED EDGE A

GLUED EDGE B

PEDMARK, for intravenous use

INDICATIONS AND USAGE

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Limitations of Use

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- Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.
- PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.
- Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.
- Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m^2.
- Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.
- The most common adverse reactions (≥25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (≥25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

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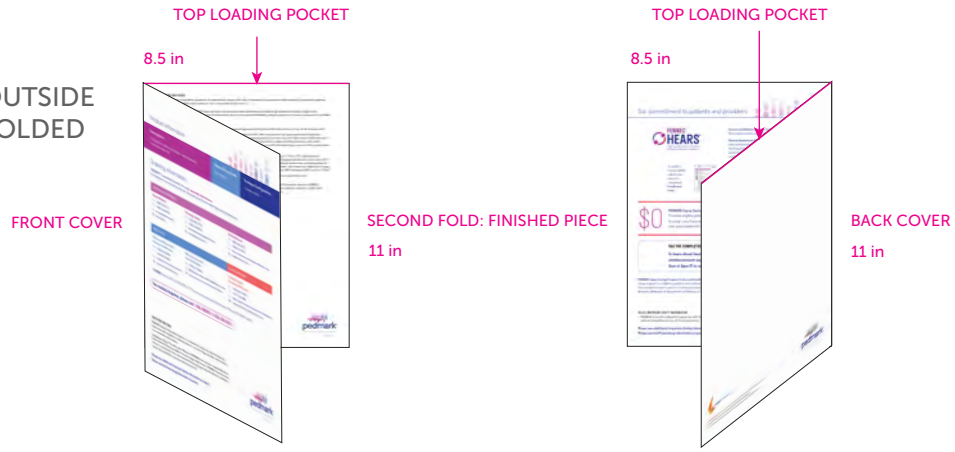
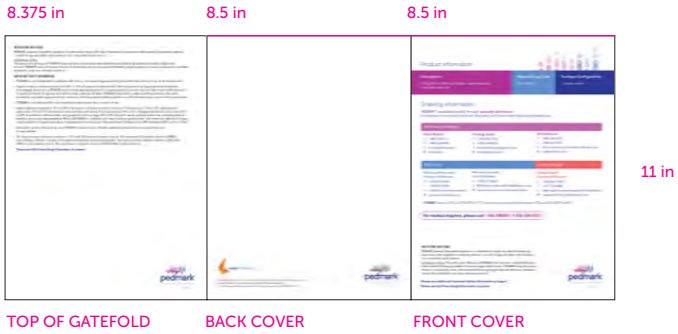
4-PAGE FLASHCARD FOLDED, GLUED, ASSEMBLED WITH PI POCKET

OUTSIDE FOLDED

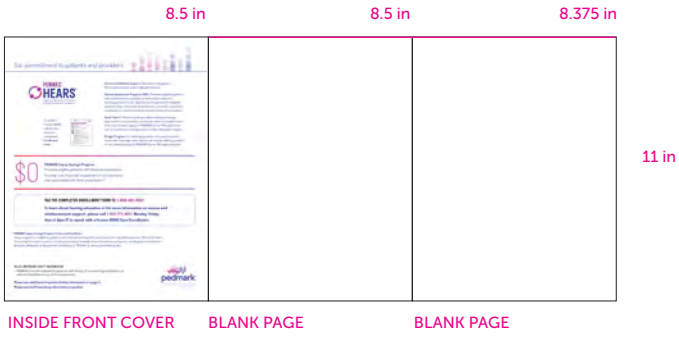


FLAT (PRINTER)

OUTSIDE PRINTED SURFACE FLAT



INSIDE PRINTED SURFACE FLAT



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